

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

<p>IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION</p> <p>THIS DOCUMENT RELATES TO:</p> <p><i>The City of New York v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 04-CV-06054</p> <p><i>County of Albany v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0425</p> <p><i>County of Allegany v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0236</p> <p><i>County of Broome v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0456</p> <p><i>County of Cattaraugus v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0256</p> <p><i>County of Cayuga v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0423</p> <p><i>County of Chautauqua v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0214</p> <p><i>County of Chemung v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-6744</p> <p><i>County of Chenango v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0354</p> <p><i>County of Columbia v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0867</p> <p><i>County of Cortland v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0881</p> <p><i>County of Dutchess v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 05-CV-6458</p> <p><i>County of Essex v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0878</p> <p><i>County of Fulton v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0519</p>	<p>MDL NO. 1456 Civil Action No. 01-12257-PBS</p> <p>Judge Patti B. Saris</p> <p>PLAINTIFFS' OPPOSITION TO DEFENDANT AMGEN INC'S INDIVIDUAL MEMORANDUM IN SUPPORT OF MOTION TO DISMISS</p>
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County of Genesee v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-00267

County of Greene v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0474

County of Herkimer v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00415

County of Jefferson v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0715

County of Lewis v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0839

County of Madison v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00714

County of Monroe v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6148

County of Nassau v. Abbott Laboratories, Inc., et al.
E.D.N.Y. Case No. 04-CV-05126

County of Niagara v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06296

County of Oneida v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0489

County of Onondaga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0088

County of Ontario v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6373

County of Orleans v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6371

County of Putnam v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 05-CV-04740

County of Rensselaer v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00422

County of Rockland v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 03-CV-7055

County of Schuyler v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6387

County of Seneca v. Abbott Laboratories, Inc., et al.

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County of St. Lawrence v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0479

County of Saratoga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0478

County of Steuben v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6223

County of Suffolk v. Abbott Laboratories, Inc., et al.
E.D.N.Y. Case No. 03-CV-12257

County of Tompkins v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0397

County of Ulster v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 06-CV-0123

County of Warren v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0468

County of Washington v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0408

County of Wayne v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06138

County of Westchester v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 03-CV-6178

County of Wyoming v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6379

County of Yates v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06172

INTRODUCTION

Amgen Inc.'s ("Amgen") individual memorandum (hereinafter "Amgen MTD") seeks the dismissal of plaintiffs' fraud-based claims on the grounds that: (i) plaintiffs' allegations are insufficient under Fed. R. Civ. P. 9(b) due to plaintiffs' failure to state the basis for calculating the spread applicable to Amgen drugs; and, (ii) plaintiffs' allegations are insufficient under Fed. R. Civ. P. 8(a) and 9(b) because Amgen drugs Epopen, Infergen and Neupogen are exclusively or almost solely physician-administered drugs and reimbursed at actual cost.

Plaintiffs allege fraudulent AWPs for all Amgen drugs for which they seek relief and properly use generally available market prices to demonstrate the inflated Amgen spreads.¹ This specificity satisfies the particularity requirements of Fed R. Civ. P. 9(b) as well as the Court's prior rulings, including in the matter styled *County of Suffolk v. Abbott Labs., et al.*² Plaintiffs' claims for physician-administered drugs are not extinguished by New York law requiring reimbursement at actual cost. Claims relating to Amgen physician-administered drugs reimbursed based on fraudulent AWPS and WACs should be sustained as they satisfy Fed. R. Civ. P. 8(a) and 9(b) and the Court's prior rulings.³

DISCUSSION

A. Plaintiffs' Fraud-Based AWP Claims Are Pled With Sufficient Particularity

¹See Corrected Consolidated Complaint, filed on June 22, 2005 ("Consolidated Complaint" or "CC") at ¶¶223-5, 230, 234-8, CC Exh. A & B; Nassau Second Amended Complaint, filed on January 6, 2006 ("Nassau SAC" or "NSAC") at ¶¶ 210 - 211, 228, 232-234, NSAC Exh. A & B.

² See *In re Pharm. Indus. Average Wholesale Price Litig.*, 339 F.Supp.2d 165, 173 ("Suffolk I"); *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 01-12257, 2004 WL 2387125, at *3 (D. Mass. Oct. 26, 2004) ("Suffolk II"); *In re Pharm. Indus. Average Wholesale Price Litig.*, Memorandum and Order at 1-2 (D. Mass. April 8, 2005) ("Suffolk III").

³ All other causes are addressed in Plaintiffs Consolidated Opposition to Defendants Motion to Dismiss, filed contemporaneously herewith. Insofar as Amgen incorporates Merck & Co.'s individual brief, plaintiffs address those arguments in their opposition to Merck's individual motion to dismiss, which opposition is incorporated herein. That brief is also being filed contemporaneously. Lastly, plaintiffs agree that Amgen's subsidiary Immunex is represented by separate counsel. Plaintiffs only address drugs manufactured exclusively by the Amgen parent in this brief since those are the only drugs Amgen's motion addresses. See Amgen MTD at 4, n.4.

Amgen contends that plaintiffs allege a “mysterious sales price” and plaintiffs do not adequately plead the basis for their spread calculations. *See Amgen MTD at 4.*

The market price, however, is no “mystery.” Plaintiffs already informed the Court and all defendants, including Amgen, that the prices used to calculate spreads were actual market prices offered to Ven-a-Care of the Florida Keys, Inc. (“Ven-a-Care”), a licensed pharmacy, and available on a nationwide basis to similar pharmacies participating in the McKesson/Servall program.⁴ *See Plaintiffs’ Response to Defendants’ Request for Extension of Time and Further Relief in Order to Comply with July 8, 2005 Order* (filed October 12, 2005). Furthermore, in the matter styled, *State of California ex rel. Ven-a-Care of the Florida Keys v. Abbott Labs., et al.*, also pending before this Court, plaintiffs there used the same prices to calculate the spreads in support of similar claims against various drug manufacturers, including Amgen. The legitimacy and source of the same prices used to calculate spread were not questioned by any defendant in recently filed motions to dismiss in that action.

For plaintiffs to maintain fraud-based AWP Claims, plaintiffs must set forth factual allegations regarding spread, internal documents or government investigations from which an inference of fraud can reasonably be made. *See Suffolk II* 2004 WL 2387125, at *2; *In re Pharm. Indus. Average Wholesale Price Litig.*, 307 F. Supp. 2d 196, 209 (D. Mass. 2004) (“*Pharm. II*”). In alleging a spread, using a calculated actual average sales price for a drug will not suffice. *See Suffolk III* at 2.

Plaintiffs have satisfied these requirements. Plaintiffs (1) provide fraudulent AWPs (and

⁴Amgen’s ignorance of McKesson/ServAll is disingenuous. *See Amgen MTD at fn. 4.* From 1994 to at least 2003, McKesson/ServAll was a joint venture between McKesson, one of the top 3 largest drug wholesalers, and ServAll, one of the largest group purchasing organization representing well over 3000 independent pharmacies. *See* [*www.query.nytimes.com/gst/fullpage.html?res=9C04E3D91331F933A25751C0A9679C8B63*](http://www.query.nytimes.com/gst/fullpage.html?res=9C04E3D91331F933A25751C0A9679C8B63). And Amgen’s contention that they cannot relate the Ven-a-Care prices to prices in their own databases inappropriately engages a factual dispute (easily resolved with discovery). Amgen does not say what its prices are, and has not supplied plaintiffs with these numbers.

spreads) for all Amgen products for which plaintiffs paid (*see CC ¶¶223-5, 230, 234-8, CC Exh. A & B; NSAC ¶¶ 210 - 211, 228, 232-234, NSAC Exh. A & B;*⁵ (2) show that Amgen admitted to setting its AWPs in its answer to the complaint in the matter styled *In re Pharmaceutical Industry Wholesale Price Litigation* also pending before this Court (*see CC ¶141, NSAC ¶219*); (3) detail exorbitant spreads calculated based on actual available market prices -- not a calculated average price for Amgen products; (4) allege that Amgen VP Edward Morrow stated that Amgen was moving from a “drug revenue model” to the “drug service model” because Amgen was losing the ability to create whatever spread it likes by setting both the acquisition cost and reimbursement rate for its drugs (*see CC ¶229; NSAC 227*); (5) allege that Amgen is keenly aware that its purchasers’ profits depend on the reimbursement rates of Amgen drugs as it acknowledged in its 2002 SEC Form 10k (*see CC ¶240; NSAC 218*);⁶ (6) allege that Amgen pursued aggressive discounting of Aranesp in a pricing war, yet the AWP never decreased (*see CC ¶231-234; NSAC ¶¶228-231*); (7) show that Amgen’s exorbitant spreads are often well over 200% (*see CC ¶¶223-5, 230, 234-8, Exh. A & B; NSAC ¶¶ 210 - 211, 228, 232-234, Exh. A & B.*; and (8) properly allege and refer to government investigations concerning Medicaid and pricing practices of Amgen Group being conducted by the Senate Finance Committee, the DOJ, the HHS OIG, the House Committee on Energy and Commerce, and the States of Pennsylvania and Wisconsin (*see CC ¶242, NSAC 222-224*).

The foregoing is certainly sufficient to draw a reasonable and sound inference of a company-wide AWP Fraud in compliance with the requirements of Fed. R. Civ. P. 9(b). *See*

⁵Plaintiffs do not waive any arguments regarding Immunex drugs but do not address such drugs here since Amgen’s motion concerns only those drugs Amgen admits to manufacturing. Plaintiffs expressly reserve the right to revisit the question of Amgen’s liability for Immunex’s drugs when/if that issue becomes ripe.

⁶Plaintiffs’ allegations relating to Aranesp and Neulasta show fraudulent AWPs and exorbitant spreads that resulted in plaintiffs being overcharged for these drugs. *See CC ¶230-234; NSAC ¶¶228-231.*

U.S. ex rel Franklin v. Parke Davis, 147 F.Supp.2d 39, 49 (D.Mass. 2001)(Saris, J.) (“[W]here the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible.”). Plaintiffs’ AWP fraud claims should be sustained.

B. Plaintiffs’ Fraud-Based Best Price Claims Are Pled With Sufficient Particularity.

In order to maintain Best Price claims, plaintiffs must “set forth minimal facts with respect to (1) the allegedly fraudulent or false price reported to the state for any specific drug; or (2) any information showing a company-wide scheme to misstate Best Prices.” *Suffolk II*, 2004 WL 2387125, at *3.

Plaintiffs did both. First, plaintiffs allege the name of every Amgen drug for which they assert Best Price claims. *See CC ¶¶ 223-245, Exh. A & B; NSAC ¶¶ 210-234, Exh. A & B.* Second, plaintiffs allege a company-wide scheme and strategy to use aggressive discounts and off-invoice pricing to lower the net cost to the purchaser while concealing the actual cost. *See CC ¶ 153; NSAC ¶ 122.* Among other allegations of malfeasance, plaintiffs allege that: (1) Amgen utilized aggressive discounts, off-invoice pricing and bundled discounts on various products; (2) Amgen maintained that price adjustment and off-invoice discounting were required to retain market share and profitability; (4) Amgen is keenly aware that its purchaser’s profits depend on the reimbursement rates of Amgen drugs; (5) Amgen utilized, and did not account for, off-invoice price reductions in the form of marketing grants, special educational grants and/or data gathering fees, the effect of which was to mask the true cost of the drugs and maintain a higher fictional invoice price. These allegations, with those in Point A *supra*, show a company-wide scheme implicating all Amgen products. *See CC ¶¶ 153, 223-245, Exh. A & B; NSAC ¶¶ 122, 210-234, Exh. A & B.*

C. Plaintiffs Claims Apply to All Physician-Administered Drugs

Amgen contends that all claims for exclusively physician-administered drugs (“PADs”) should be dismissed because under New York law PADS are reimbursed at actual cost. *See*

Amgen MTD at 4-5.

Plaintiffs assert their claims against Amgen “from 1992 to the present.” CC ¶1; NSAC ¶1. New York did not begin reimbursing PADs based on actual cost until it amended the Medicaid reimbursement scheme on June 9, 1994. *See N.Y. Soc. Serv. L. § 367-a(9)(a)* (1994 amendments). Prior to June 9, 1994, New York reimbursed PADs based on fraudulent AWPs. As such, all fraud-based claims between 1992 and June 9, 1994 must be sustained. Additionally, irrespective of the amendment, to the extent PADs can also be self-administered they are reimbursed based on fraudulent AWPs and plaintiffs’ theory of fraud and injury applies. Currently, there is no record before the Court that can be used to determine which of Amgen’s PADs are also self-administered and therefore reimbursed based on fraudulent AWPs. Thus, the claims should be sustained until the record is developed and presented to the trier of fact.

In addition, the settlement between the State of New York and TAP regarding the marketing, sale and pricing of Lupron (the “2001 Lupron Settlement”) calls into question whether physicians in New York are, in fact, reimbursed based on “actual cost” or AWP. In the context of the 2001 settlement, the State of New York alleged that Lupron’s reimbursement was based on reported AWP (despite the New York State statute mandating that PADs are reimbursed at acquisition cost). This allegation by the state itself calls in to question how PADS are reimbursed by Medicaid. It is a fact question not appropriately resolved here.

D. Other Claims.

Finally, Amgen does not dispute that at barest minimum plaintiffs’ allegations state AWP and Best Price unjust enrichment claims, and claims for 18 N.Y.C.R.R. §515.2(b)(4) & (5). The Court ruled that Rule 9(b) does not apply to such claims. *Suffolk II*, 2004 WL 2387125, at *2.

CONCLUSION

For the foregoing reasons, Amgen’s individual motion to dismiss should be denied in its entirety.

Dated: April 17, 2006

Respectfully submitted,

**City of New York and all captioned Counties
except Nassau, by**

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